



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,827	03/10/2004	Linda M. Weigel	6395-68161-01	5019
46135 7590 05/03/2007 KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET SUITE 1600 PORTLAND, OR 97204			EXAMINER LU, FRANK WEI MIN	
			ART UNIT 1634	PAPER NUMBER
			MAIL DATE 05/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/798,827

Applicant(s)

WEIGEL ET AL.

Examiner

Frank W. Lu

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-41 is/are pending in the application.
- 4a) Of the above claim(s) 32-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 30,31 and 39-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of SEQ ID NO: 9 in the reply filed on February 7, 2007 is acknowledged. The traversal is on the ground(s) that "[T]he nucleotide sequences shown in SEQ ID NOs: 9-16 are the quinolone resistance determining region (QRDR) sequences from the *gyrA* gene of Enterobacteriaceae species. Relative to the *E. coli* sequences, the QRDR sequence corresponds to nucleotides 199 to 318 of the *gyrA* gene. The claimed methods are directed to determining the quinolone resistance status of *Enterobacteriaceae* species. Simultaneous identification of the species and mutations leading to resistance can be determined using probes described in the specification (see for example, page 21, line 30 to page 22, line 2, and Tables 3 and 4, found on pages 21 and 22, respectively). Generally, susceptible strains will hybridize to the probe and resistance is detected by a one or more base pair mismatch. Exemplary probes that can be used to determine the quinolone resistance status, namely SEQ ID NOs: 25-33 (that correspond to 25 nucleotides of one of SEQ ID NOs: 1-9), are disclosed in specification in Table 4. The specification discloses that the amino acid sequences of the QRDR polypeptides encoded by SEQ ID NOs: 9-16 are very related (and many are identical). The polypeptide encoded by SEQ ID NO: 9 is 100% identical to the polypeptides encoded by SEQ ID NO: 12, SEQ ID NO: 14 and SEQ ID NO: 16. The polypeptide encoded by SEQ ID NO: 9 differs by only one amino acid from the polypeptide encoded by SEQ ID NO: 10, SEQ ID NO: 11 and SEQ ID NO: 13. The polypeptide encoded by SEQ ID NO: 9 differs by only two amino acids from SEQ ID NO: 15 (see page 18, lines 13-24). The nucleotide sequence set forth as SEQ ID NO: 9 (the *E. coli* sequence) is disclosed to be 93.3% identical to *E. cloacae* (SEQ ID NO:

Art Unit: 1634

12) and 80.8% identical to *P. stuartii* (SEQ ID NO: 15) (see page 17, lines 13-23). An alignment of QRDR sequences set forth as SEQ ID NOs: 9-16 is shown in Figure 2. Thus, the specification clearly discloses that these sequences are structurally related. MPEP § 2434 states: '[n]ucleotide sequences encoding the same protein are not considered to be independent and distinct and will continue to be examined together.' Thus, it is clear that SEQ ID NO: 9 should be examined with SEQ ID NO: 12, SEQ ID NO: 14 and SEQ ID NO: 16. In addition, as the QRDR proteins encoded by SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 13 and SEQ ID NO: 15 differ from the polypeptide encoded by SEQ ID NO: 9 by at most two amino acids, Applicants submit that all of SEQ ID NOs: 9-14 should be examined a single application. It would not represent a burden on the Patent Office to examine the closely related sequences in a single patent application. Applicants believe that these sequences should still be examined together in view of the sequence similarity of SEQ ID NOs: 9-14 at the nucleotide level,. MPEP § 2434 also states: '...the Commissioner has partially waived the requirements of 37 CFR 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, in most cases, up to 10 independent and distinct nucleotide sequences will be examined in a single application without restriction'.”.

The above arguments have been fully considered and have not been found persuasive toward the withdrawal of the lack unity requirement nor persuasive toward the relaxation of same such that SEQ ID NO: 9-16 will be examined together. First, although the nucleotide sequences shown in SEQ ID NOs: 9-16 may be the quinolone resistance determining region (QRDR) sequences from the *gyrA* gene of *Enterobacteriaceae* species and relative to the *E. coli* sequences, the QRDR sequence corresponds to nucleotides 199 to 318 of the *gyrA* gene, since

Art Unit: 1634

the *Enterobacteriaceae* are a large family of bacteria, including many of the more familiar pathogens, such as *Salmonella* and *Escherichia coli* (see attached definition for *Enterobacteriaceae*) and SEQ ID NOs: 9-16 are from gyrase A gene from *Escherichia coli*, *Citrobacter freundii*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Providencia stuartii*, and *Serratia marcescens* respectively wherein *Escherichia coli*, *Citrobacter freundii*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Providencia stuartii*, and *Serratia marcescens* are different bacteria which have different biological properties, SEQ ID Nos: 9-16 are patentably distinct sequences. Second, although applicant argues that “the polypeptide encoded by SEQ ID NO: 9 is 100% identical to the polypeptides encoded by SEQ ID NO: 12, SEQ ID NO: 14 and SEQ ID NO: 16. The polypeptide encoded by SEQ ID NO: 9 differs by only one amino acid from the polypeptide encoded by SEQ ID NO: 10, SEQ ID NO: 11 and SEQ ID NO: 13. The polypeptide encoded by SEQ ID NO: 9 differs by only two amino acids from SEQ ID NO: 15”, since the claims are directed to a method related to nucleic acids and are not directed to a method related to polypeptides, applicant appears to compare an apple (ie., polypeptide) to an orange (ie., nucleic acid). Third, MPEP 2434 states that “[N]ucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121”. Although the examiner agrees with applicant that “[N]ucleotide sequences encoding the same protein are not considered to be independent and distinct and will continue to be examined together”, since SEQ ID NOs: 9-16 are from gyrase A gene from *Escherichia coli*, *Citrobacter freundii*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Klebsiella oxytoca*,

Art Unit: 1634

Klebsiella pneumoniae, *Providencia stuartii*, and *Serratia marcescens* respectively wherein *Escherichia coli*, *Citrobacter freundii*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Providencia stuartii*, and *Serratia marcescens* are different bacteria which have different biological properties, SEQ ID Nos: 9-16 are patentably distinct sequences and SEQ ID NOs: 9-16 are not from a single gene, according to MPEP 2434, SEQ ID Nos: 9-16 should be restricted to different groups. Fourth, although MPEP 2434 states that “the Commissioner has partially waived the requirements of 37 CFR 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, in most cases, up to 10 independent and distinct nucleotide sequences will be examined in a single application without restriction”, MPEP 2434 does not require that the examiner must examine 10 independent and distinct nucleotide sequences together as argued by applicant. Based on above reasons, the requirement is still deemed proper and is therefore made FINAL.

2. Sequence Election Requirement

After further reviewing newly added claims 39-41, the examiner notes that claims 39 and 41 contain patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Applicant is advised that examination will be restricted to only elected SEQ ID NO. in claims 39 and 41 and should not to be construed as a species election.

3. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

Art Unit: 1634

(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

April 30, 2007

A handwritten signature in black ink, appearing to read 'Frank Lu', is positioned above the printed name.

FRANK LU
PRIMARY EXAMINER